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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,159	02/05/2002	Bernard Bihain	29.US4.DIV	2627

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EXAMINER	
CHANDRA, GYAN	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/072,159	**Applicant(s)** BIHAIN ET AL.	
	Examiner Gyan Chandra	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *91-109*.

   Claim(s) withdrawn from consideration: *110-115*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continued sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 09/09/2005
13. ☐ Other: _____.

Continuation of 11 does not place the application in condition for allowance because:

Applicant's Response to Final Rejection filed on 09/09/05 is acknowledged. The Information Disclosure Statement (IDS) filed on 09/09/05 has been considered.

The rejection of claim 91 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for the reasons of records in the Office Action filed on 6/15/2005.
Applicants cite Enzo Biochem, Inc. v. Gen-Probe Inc. and argue that written description can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics. However the claims are drawn to a method of increasing the partitioning of dietary lipids between the liver and peripheral tissues comprising the administration of an agent having at least 80% homology to APM1 and SEQ ID NOs: 7, 8,9, 10, 11...or 14. The specification does not provide support to amino acid residues required for increasing the partitioning of dietary lipids between the liver and peripheral tissues. One skill of the Arts would not be able to make mutations, substitutions or deletions in the claimed sequences in order to have the ability of increasing the partitioning of dietary lipids between the liver and peripheral tissues.There is no discloser for identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolating it. The compound itself is required.

The rejection of claims 91-109 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the partitioning of dietary lipids between the liver and peripheral tissue comprising the administration of ApM1, does not reasonably provide enablement for a method of increasing the partitioning of dietary lipids between the liver and peripheral tissue comprising the administration of a polypeptides of at least 80% sequence homology with the SEQ ID NOs. 7, 8, 9,.... and 14, is maintained for the reasons of records in previous office actions.
Applicants points to a later filed sequence in GenBank in year 1999 with Accession numbers D45371 and BAA08227. Applicants sequence list does not include theses sequences, therefore a meaningful sequence search or sequence comparision can not be performed. Further, Applicants point to three post filing research articles (Bloomgarden, 2002, Steinberger, 2003 and De Jongh 2004) that obesity is related to atherosclerosis, diabetes Type II, hypertension and diabetes related microangiopathy.
Applicants arguments have been fully considered but the are not convinsing because the specification does not enable one skill in the art for a method of increasing the partitioning of dietary lipids between the liver and peripheral tissue comprising the administration of a polypeptides of at least 80% sequence homology with the SEQ ID NOs. 7, 8, 9,.... and 14. The specification does not disclose any working example that can predict functional out come of a mutation in polypeptides with the SEQ ID NOs. 7, 8, 9,.... and 14 . Once a mutation has been made in polypeptides with the SEQ ID NOs. 7, 8, 9,.... and 1, it will require large amount of experimentation to determine its functional consequences. There is no guidance to how well a mutant would impact reducing plasma triglyceride levels in vivo so that it can be used in a patient to increase partitioning of dietary lipids between the liver and peripheral tissues. It is unpredictable to substitute an amino acid with another amino acid without any loss in functionality.

Applicants newly filed claims 110-115 are drawn to a non-elected method of treating condition. Therefore, thes claims will not be entered in the record.

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER